

REMARKS

Claims 1-37 and 48-50 were pending in the present application. Claims 1-27, 48 and 49 were withdrawn from consideration. By virtue of this response, claim 50 is amended. Accordingly, claims 1-37 and 48-50 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter has been added. Support for the amendment to claim 50 may be found in the specification as filed. For example, see page 2, line 30 through page 3, line 8; and page 9, lines 25-30.

Concerning the drawings

Applicant requests entry of the attached replacement drawings. Applicant has removed the stray lines referred mentioned in the previous Office Action.

Interview Summary

Applicant's attorney wishes to express gratitude to the Examiner for the telephone interview of February 27, 2006. The participants included applicant's representative, Sanjay Bagade and Examiner David Shay.

No exhibit was shown.

At this interview, the parties discussed the rejection of claims 50 in view unpatentable over Clarke (U.S. Patent No. 5,053,033) in combination with Waksman et al. (International Publication No. WO 97/33715). Applicant submitted that the amendment to claim 50, as provided above, overcomes the previous rejection.

The Examiner indicated his agreement with respect to the Clarke and Waksman references but indicated the need for an additional search.

Rejections under 35 U.S.C. §103(a)

Claims 28-37 and 50 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Clarke (U.S. Patent No. 5,053,033) in combination with Waksman et al. (International Publication No. WO 97/33715).

As noted above in the Interview Summary, applicant believes this rejection is traversed.

Additional Matters – Information Disclosure Statement

Applicant also wishes to bring to the Examiner's attention, related applications and patents commonly assigned to the assignee of the present invention:

U.S. Publication No. US-2002-0091379-A1, published July 11, 2002;

U.S. Publication No. US-2004-0031494-A1, published February 19, 2004;

U.S. Publication No. US-2004-0182399-A1, published September 23, 2004;

U.S. Publication No. US-2005-0010270-A1, published January 13, 2005;

U.S. Patent No. 6,411,852, issued June 25, 2002;

U.S. Patent No. 6,488,673, issued December 3, 2002; and

U.S. Patent No. 6,634,363, issued October 21, 2003

Applicant is further submitting an Information Disclosure Statement to submit references cited in commonly assigned applications. In order to expedite prosecution of the subject application, applicant is submitting comments regarding several of the references cited in the Information Disclosure Statement.

Regarding Osin A Ya RU 2091054

Applicant provides an English translation of Osin ("Osin Translation") with this response. From page 3 (first paragraph) of the Osin Translation, Osin teaches exposing a low-power light of helium-neon laser on the mucosa of the upper respiratory tracts, the projection of the thymus, paravertebrally, and in the adrenal region, and areas with allergic skin affection in children The reference continues to teach that "[w]hen this [treatment] is done, what occurs are a direct effect on the afflicted areas of the skin and mucosa of the upper respiratory tracts, correction of disruptions of the nonspecific defense and immunity systems, stimulation of the adrenal glands and a reflexogenic effect on the bronchopulmonary system." (emphasis added, Osin Translation, page 3, first partial paragraph.)

Osin teaches application of a low power light of a helium-neon laser on the mucosa of upper respiratory tracts¹ (i.e., the nose or nostrils, nasal cavity, mouth, pharynx, or larynx.) In contrast, claim 50 requires irradiating the walls of an airway of the lung. Clearly, claim 50 recites a method that is carried out on an airway of the patient's lungs. Applicant is unable to find in Osin any teaching or suggestion for such a requirement.

Furthermore, Osin teaches the result of that treatment as having a direct effect on the afflicted areas of the skin and mucosa of the upper respiratory tracts, correction of disruptions of the nonspecific defense and immunity systems, stimulation of the adrenal glands and a reflexogenic effect on the bronchopulmonary system. Applicant is unable to find, in Osin, that the treatment causes debulking of the lung tissue and prevents the lung tissue from replicating.

Regarding Provotorov et al.

Applicant next refers to Provotorov et al. "The Clinical Efficacy of Treating Patients with Nonspecific Lung Disease using Low-Energy Laser Irradiation and Intrapulmonary Drug Administration." (Provotorov) Again, applicant is providing a translation of Provotorov ("Provotorov Translation").

The first paragraph of the Provotorov translation states:

The traditional administration of medicinal preparations entails considerable metabolic alteration of them in the liver, and moreover the arrival of a drug that has retained its activity at the lumen of the bronchi or a lesion focus is significantly reduced by the selective permeability of the functional histohematogenous barrier of the bronchial mucosa and the inflammation-altered peribronchial pulmonary parenchyma (the pathologic histohematogenous barrier). In many cases, disruption of microcirculation at a lesion focus may lead to blockage of the arrival of drugs at the bronchial lumen and the inflammation focus of the pulmonary parenchyma, disruption of repair processes, and the development of disseminated intravascular coagulation (DIC) syndrome in the arterioles and capillaries [5, 6, 9]. *(emphasis added)*

¹ Applicant believes that most standard widely available dictionaries define "upper respiratory tract" as the part of the respiratory system including the nose, nasal passages, and nasopharynx. See for example: <http://www.onelook.com> or the encyclopedia and dictionary at <http://www.medlineplus.gov/>. For convenience, applicant provides herewith Attachment 1, a page from the Medline Plus site defining "Upper Respiratory Tract."

Provotorov continues to disclose (in the 3rd paragraph on the first page of the Provotorov translation):

When NPD patients are exposed to low-intensity coherent monochromatic light, a number of clinical effects are observed in the organs and tissues: capillary blood flow, lymph circulation, and fibrinolysis are stimulated, underlying which is a mitogenic response due to local depolarization of the membrane [2, 5]. The penetration of drugs both across the physiological histohematogenous barrier of the bronchial mucosa and across the pathologic barrier — the inflammation-altered pulmonary parenchyma [9, 12] — is stimulated. The anti-inflammatory and analgesic effect of radiation and its ability to stimulate cellular and tissue trophic processes are observed [9, 11, 12]. Immunologic reactivity and the interferon system are optimized, and a general adaptive effect is observed [4, 7, 10]. And finally, laser irradiation has a direct broncholytic and mucolytic effect [6, 12].

Given a full reading of the cited article, applicant believes that the Provotorov publication merely teaches application of a low-intensity laser to alter a histohematogeneous barrier of the bronchial mucosa stimulating the penetration of drugs across the mucosa. Applicant submits that the Provotorov reference teaches application of energy to mucosa to allow for improved drug transport across the barrier.

RU 2053814 to Novikov

Applicant is providing a translation of Novikov (“Novikov Translation”). In the Novikov Translation, page 1, paragraph 5, Novikov teaches the object of the invention as being:

. . . attained by stimulating the defense mechanisms in the donor section with monochromatic light of a low-power helium-neon laser and then transplanting into the affected area, after it is washed with a 0.85% sodium chloride solution, the set of activated pulmonary defense factors and surfactant obtained by using a selective bronchoalveolar lavage from one segment of the donor section. The novelty of the method consists in the simultaneous transplantation of the entire set of pulmonary defense factors stimulated by irradiation with a low-power helium–neon laser. *(emphasis added)*

As stated, Novikov teaches stimulating defense mechanisms and then transplanting activated pulmonary defense factors to the desired area.

Vorotnev et al.

Applicant is providing a translation of Vorotnev A. I. et al., "TREATMENT OF CHRONIC OBSTRUCTIVE BRONCHITIS PATIENTS USING A LOW-POWER LASER AT A GENERAL REHABILITATION CENTER," *Terapevticheskii Arkhiv*, 3:17-19 (1997) ("Vorotnev Translation"). In the Vorotnev translation, page 5, paragraph 1, Vorotnev teaches:

Observations showed that the effectiveness of β_2 -antagonists increases against the background of LT. The data can be explained by increasing the sensitivity of the bronchial β_2 -receptors to sympathomimetics after LT, which is consistent with the published data [1].

Applicant believes, Vorotnev is not relevant to the claims in the subject application.

Ivaniuta et al.

Applicant is providing a translation of Ivanyuta, O. M. et al., "EFFECT OF LOW-POWER LASER IRRADIATION OF BRONCHIAL MUCOSA ON THE STATE OF SYSTEMIC AND LOCAL IMMUNITY IN PATIENTS WITH CHRONIC BRONCHITIS," *Problemy Tuberkuleza*, 6:26-29 (1991) ("Ivanyuta Translation").

In the Ivaniuta Translation, page 2, paragraph 1, Ivaniuta teaches:

The ability of the laser to affect both the pathologic process and immunocompetent cells has been proved. At the same time, the efficacy of endobronchial laser irradiation in chronic bronchitis has received little study, and there are not enough data on the effect of this kind of laser therapy on the state of systemic and local immunity.

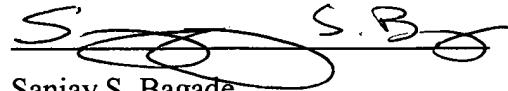
Based on the foregoing, we have studied the efficacy of endobronchial low-power laser therapy and its effect on the immune status of patients with chronic nonobstructive bronchitis (CNB) in whom other methods of treatment proved ineffective.

Applicant believes, Ivaniuta is not relevant to the claims in the subject application.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'S. Bagade', with a large, stylized flourish underneath.

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